UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,148	06/24/2002	Hiroyuki Hirai	Q68584	7696

23373 7590 11/12/2003

SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
WASHINGTON, DC 20037

EXAMINER	
LANDSMAN, ROBERT S	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 11/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/069,148	HIRAI ET AL.	
	Examiner	Art Unit	
	Robert Landsman	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-4 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-4 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 22 February 2002 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5/16/03 6/24/02
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Formal Matters

A. Claims 1-4 are pending and are the subject of this Office Action.

B. The Information Disclosure Statement, filed 5/6/03, has been entered into the record.

C. The Information Disclosure Statement, filed 6/24/02, has been entered into the record.

2. Priority Data

A. The specification is objected to since the priority data (to PCT/JP00/05615) is not recited in the first line of the specification.

3. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

A. Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of identifying ligands which bind to the CRTH2 and PGD receptors, or which modulate intracellular calcium, does not reasonably provide enablement for any and all "properties" of a test compound or for all "effects" on CRTH2 and PGD receptors, or for "derivatives." The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

First, the breadth of the claims is excessive with regard to Applicants claiming a method for identifying any and all properties of a test substance or for all effects on CRTH2 and PGD receptors, or for derivatives of CRTH2. Applicants are only enabled for PGD2 binding (pages 20 and 23 – Examples 3 and 5), intracellular calcium (page 22 – Example 4) and receptor downregulation (page 23-24 – Example 6). Applicants provide no guidance or working examples of any other "properties" or "effects," nor do

they provide any guidance or working examples of any "derivative" of CRTH2 other than the full-length receptor. Furthermore, Applicants have not taught the use of any CRTH2 receptor other than the full-length CRTH2 receptor. Applicants have not taught which residues are critical for receptor function and, therefore, which residues can be altered and still retain the function of the full-length receptor. CRTH2 receptors other than that of the full-length CRTH2 would have one or more amino acid substitutions, deletions, insertions and/or additions to the CRTH2 receptor. Furthermore, it is not predictable to the artisan what other effects could be measured other than the binding of radiolabeled PGD or that of intracellular calcium, nor could the artisan predict how to make a functional CRTH2 receptor other than that of the full-length human receptor disclosed in the specification.

In summary, the breadth of the claims is excessive with regard to Applicants claiming a method for identifying any and all properties of a test substance or for all effects on CRTH2 and PGD receptors, or for derivatives of CRTH2. Applicants are only enabled for PGD2 binding, intracellular calcium and receptor downregulation using the full-length CRTH2 receptor. Furthermore, it is not predictable to the artisan what other effects could be measured other than the binding of radiolabeled PGD or that of intracellular calcium, nor could the artisan predict how to make a functional CRTH2 receptor other than that of the full-length human receptor disclosed in the specification. For these reasons the Examiner holds that undue experimentation would be required to practice the claimed invention.

4. Claim Rejections - 35 USC § 112, first paragraph – written description

A. Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These are genus claims. Applicants have not provided adequate written description for any and all "properties" of a test compound or for all "effects" on CRTH2 and PGD receptors, or for "derivatives" of CRTH2 receptors. CRTH2 receptors (i.e. derivatives) other than that of the full-length CRTH2 would have one or more amino acid substitutions, deletions, insertions and/or additions to the CRTH2 receptor. The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus of "properties," "effects" or "derivatives." Thus the scope of the claims includes numerous variants of "properties" and "effects," including structural variants of these derivatives, and these genii are highly variant because a significant number of structural and functional differences between genus members is permitted. The specification and claims do not provide any guidance as to what changes should be made to the full-length CRTH2 receptor, or as to what "properties" and "effects" are to be

measured. Structural features that could distinguish compounds in the genus from others in the protein class are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, "properties," "effects" and "derivatives" alone are insufficient to describe the genus. One of skill in the art would reasonable conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus at the time the invention was made.

5. Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: a conclusion step to identify when the method has been completed. Also, it is not understood what is the "property" of the test substance or the "effect" on CRTH2 and PGD. Overall, there is no clearly defined steps in any of the claims which clearly define the invention and what steps are needed to practice it.

B. Claims 1-4 are confusing since it is not clear if "CRTH2" is referring to the receptor or to the cell itself.

C. Claims 2-4 are confusing since these claim only define an assay for one of the receptors. It is not clear what "function" of the other receptor in each of these claims is being measured.

D. Claim 3 is confusing since it is not clear to what the "derivative thereof" is referring. If the derivative is to CRTH2, it is not clear if this is to a cell, or to the receptor.

6. Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

A. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al. (US 20020022218). The claims recite a method of identifying a property of a test substrate with respect to hPGD receptor by correlating an effect of the substance on hCRTH2 with an effect of the substance on hPGD receptor. The method includes the use of binding affinity and in site agonist/antagonist ability.

Li et al. teach that PGD binds the CRTH2 receptor and teach assay methods for identifying agonists and antagonists of this interaction, including binding affinity and in situ assays (aragraphs [0013]-[0020], [0045], [0076] – [0080] and [0108]). Li do not teach the method of the present invention in which the PGD receptor is used and the binding of a test compound to that receptor is compared to that of the CRTH2 receptor. However, it would have been obvious to one of ordinary skill in the art at the time of the present invention to have used a method to screen ligands for their ability to bind to both the PGD receptor and CRTH2 receptor. Li teach that PGD binds both the PGD receptor and the CRTH receptor. Therefore, it would have been obvious at the time to have identified compounds which act at both the PGD and CRTH2 receptors in order to identify ligands which selectively bind one of the receptors or to identify compounds which have a higher affinity for one or the other receptors as compared to PGD.

7. Conclusion

A. No claim is allowable.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
November 10, 2003